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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,667	02/28/2002	A. John Bramley	2001796-0008	7908

24280 7590 09/08/2003

Choate, Hall & Stewart  
Exchange Place  
53 State Street  
Boston, MA 02109

EXAMINER
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WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

*id*

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/087,667

Applicant(s)

BRAMLEY ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-49 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This application filed February 28, 2002, is a continuation-in-part of application 09.337,079, filed June 21, 1999, now abandoned, which claims benefit to provisional application 60/090,175, filed June 22, 1998.

Applicants' amendment filed June 20, 2003, paper number 9, has been received and entered. Claims 26-31 and 50-64 have been canceled. Claims 32-46 have been amended. Claims 32-46 are pending and currently under examination.

### ***Election/Restriction***

Applicants election of Group II drawn to non-human transgenic mammal comprising an altered non-mammalian anti-microbial gene is acknowledged. It is noted that claim 32 has been amended from encompassing an anti-microbial gene to an anti-staphylococcal gene. This new term is broader than originally presented as exemplified in claim 42 which indicates that an anti-staphylococcal protein can be an anti-microbial peptide or an anti-viral peptide (claim 41), prokaryotic peptide (claim 43) or bacterial peptide (claim 44). Upon reconsideration of the amendments to the claims a new restriction requirement is being made.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claim 45, drawn to non-human transgenic mammal comprising an altered non-mammalian nisin gene, classified in class 800, subclass 14.
- II. Claim 45, drawn to non-human transgenic mammal comprising an altered non-mammalian muramidase gene, classified in class 800, subclass 14.
- III. Claim 45, drawn to non-human transgenic mammal comprising an altered non-mammalian glucoasminidase gene, classified in class 800, subclass 14.
- IV. Claim 45, drawn to non-human transgenic mammal comprising an altered non-mammalian endopeptidase gene, classified in class 800, subclass 14.
- V. Claim 45, drawn to non-human transgenic mammal comprising an altered non-mammalian colicin gene, classified in class 800, subclass 14.
- VI. Claims 47 and 48, drawn to non-human transgenic mammal comprising an altered non-mammalian  $\beta$ -lytic protease gene, classified in class 800, subclass 14.
- VII. Claims 47 and 49, drawn to non-human transgenic mammal comprising an altered non-mammalian lysostaphin gene, classified in class 800, subclass 14.
- VIII. Claim 47, drawn to non-human transgenic mammal comprising an altered non-mammalian  $\alpha$ -lytic protease gene, classified in class 800, subclass 14.
- IX. Claim 47, drawn to non-human transgenic mammal comprising an altered non-mammalian lyt-M gene, classified in class 800, subclass 14.
- X. Claim 47, drawn to non-human transgenic mammal comprising an altered non-mammalian at 1ALE-1 gene, classified in class 800, subclass 14.

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XI. Claim 47, drawn to non-human transgenic mammal comprising an altered non-mammalian zooA gene, classified in class 800, subclass 14.

Claims 32-44 and 46 link inventions I-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 23-44 and 46. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different products. In each case each of the inventions are directed to

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different transgenic non-human mammals comprising different transgenes. The different transgenes represent materially different starting materials required to generate the transgenic mammal, and provide for different transgenic mammals materially different at a genetic level and phenotypically different if the transgene is produced and functional in said non-human mammal.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required and different from that for Groups II-XI, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Voitach

  
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